GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:5582
ANSWERED ON:29.08.2001
NEW DRUG
BALIRAM

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the procedure being adopted for the permission of new drug alongwith the normal time taken for the grant of permission for the new drug; and

(b) the names of the new drugs for which permission has been granted during this year and what is the time taken in each case?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a): Evaluation of a new drug application for market authorization is a complex process. Requirements are prescribed under rules 122 A to E and Schedule `Y` of the Drugs and Cosmetics Rules, 1945. The modalities include inter-alia initial evaluation of chemical and physical characteristics, animal toxicity, pharmacokinetics and pharmacodynamics of the drug, by the office of the D C G(I) and experts. Approval of protocols for clinical trials as well as data generated by various clinical trials, result of testing of new drug by the Central Government lab etc. is further examined. Certain Categories of the drugs viz. Anti- cancer, anti- AIDS etc. are examined on a fast track mode.

The time taken for evaluation of new drug applications varies according to the nature of the molecule/drug and the application. It may normally take more that five years for approval of an Investigation New Drug (A drug molecule not tested on human beings anywhere in the world), about 1-3 years for the first time approval of the drug already approved elsewhere and about 2-3 months for subsequent applications for already approved drugs. This is, however, subject to timely submission of all required data as per provision of Schedule `Y` of the Drugs and Cosmetics Rules.

(b): A list of New Drugs approved this year (1st January, 2001 to 30th June, 2001) is annexed.

ANNEXURE

NEW DRUGS APPROVED BY DRUG CONTROLLER GENERAL (INDIA) DURING THE PERIOD JANUARY 2001 TO 30TH JUNE 2001

S.No	NAME OF THE DRUG	CATEGORY	DATE OF RECEIPT OF APPLICATION	DATE OF APPROVAL
1.	Sildenafil Citrate	Men Erectile dysfunction	2/6/1998	8/1/2001
2.++	Triflusalcaps 30 mg	Prevention of Thromboembolism	25/6/1996	17/1/2001
3.++	Thymosin Alfa 1 Inj.	Anti Hepa-B	28/10/1994	17/1/2001
4.+	Vinorelbin Tartrate Inj.	Anti Cancer	6/2/2000	17/1/2001
5.	Clopidogrel Aggregation Inhibitor	Anti Platlet	5/7/2000	2/2/2001
6.+	Indinavir Sulphate	Anti Aids	22/5/2000	1/2/2001

7	Butenafine HCL cream 1%	Anti fungal	11/8/2000	14/2/2001
8.	Mitrazapine	Anti depression	10/4/2000	14/2/2001
9.	Doneprazal HCL	For Alzheirmer`s D.	3/12/1998	20/3/2001
10.	Mosapride	Prokenetic agent	29/3/2000	13/3/2001
11.	Bupropion SR Tab.150 mg.	Smoking cessation	12/7/2000	10/4/2001
12.	Reloxifen	Menopausal osteoporosis	13/10/1999	4/5/2001
13.+	Efavirenz 50/100/200mg	Anti HIV	27/4/2000	6/6/2001
14.	Moxifloxacin	Anti bacterial	March 1997	26/6/2001
15.	Misoprostol	Anti ulcer	3/4/1997	21/6/2001
16.+	Nelfinavir	Anti HIV	22/12/2000	29/6/2001

+ Anti cancer/anti AIDS or immunosuppressive durgs.
++ Drugs referred to ICMR and Experts